REMARKS

Claim Status

Claims 4-6, 14-19, and 22-25 are amended herein. Claims 27-29 is newly added herein. Support for the amendments can be found throughout the specification and claims as originally filed. Claims 13, and 20-21 are cancelled herein. Claims 1-3 were previously cancelled. Claims 7-10 were previously withdrawn from consideration. This listing of claims will replace all prior versions, and listings of claims, in the application.

The amendments do not constitute an admission that the previously pending claims were anticipated, obvious, non-enabled, inadequately described or indefinite. Applicant reserves the right to file cancelled subject matter in a continuation or divisional application. Applicant respectfully requests reconsideration of the claims in light of the following arguments. Applicant believes that the Application is in a condition for allowance.

I. Information Disclosure Statement

In the Office Action of August 18, 2008, the Office indicated that it lined out foreign document citation #2 in the IDS submitted on 07/10/08, and foreign document citations # 28-31 in the IDS submitted on 09/19/2007.

In a Supplemental IDS submitted after the date of this Response, Applicant will provide English translations of foreign document citation # 29 (*see* Canadian Patent Application No. 2570177), foreign document citation # 30 (*see* Canadian Patent Application No. 2603763), and foreign document citation # 31 (*see* Canadian Patent Application No. 2603959).

No English translation of foreign document citation # 28 is available. The English language abstract of foreign document citation # 28 indicates that the invention is "[a]n apoptosis inhibitor which contains as the active ingredient 5-methyl-1-phenyl-2-(1H)-pyridone." Per MPEP 609.04(a)(III), "submission of an English language abstract of a reference may fulfill the requirement for a concise explanation." Thus, Applicant believes that the English language abstract of this reference as submitted in the IDS of 09/19/2007 satisfies the requirement for a concise explanation.

Finally, foreign document citation #2 in the IDS submitted on 07/10/08 is the PCT application from which the US application derives. As such, Applicant does not believe a translation is required for this foreign document.

II. Claim Rejections: 35 U.S.C. § 101

In the Office Action of August 18, 2008, the Office objected claims 14-16 and 20-22 under 35 U.S.C. § 101 for combining product and process limitations. The claims have herein been amended rendering the rejection moot. Thus, Applicant respectfully requests that the rejection be withdrawn.

III. Claim Rejections: 35 U.S.C. § 103

Claims 4-6 and 11-25 are rejected under 35 U.S.C. § 103(b) as being unpatentable over U.S. Patent No. 5,716,632 (Margolin I) in view of U.S. Patent No. 3,839,346 (Gadekar) and EP Patent No. 1 069 898 (Margolin II). For at least the following reasons, Applicant respectfully disagrees.

The prior art as a whole teaches away from a composition of 5-methyl-1-(4'-hydroxyphenyl)-2-(1H) pyridone

The claimed invention is a *pharmaceutical* composition comprising 5-methyl-1-(4'-hydroxyphenyl)-2-(1H) pyridone and a pharmaceutically-acceptable excipient. Per the Office Action, Margolin I teaches the compound 5-methyl-1-(4'-methoxyphenyl)-2-(1H) pyridone (*See* Office Action, page 5). The Office Action states that hydrogen and methyl are obvious variants and that "it would have been obvious to one of ordinary skill in the art to substitute hydrogen [taught in the instant application] for the methyl group" taught by Margolin I. However, Applicant asserts that the prior art as a whole teaches away from a *pharmaceutical* composition comprising 5-methyl-1-(4'-hydroxyphenyl)-2-(1H) pyridone. Per MPEP 2145(X)(D), "the prior art must be considered in its entirety, including disclosures that teach away from the claims." Further, per MPEP 2145(X)(D)(3) "the totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of non-obviousness.'

During prosecution of European Patent No. 0 702 551 (Margolin III), Margolin submitted data regarding the anti-fibrotic activity of 5-methyl-1-(4'-hydroxyphenyl)-2-(1H) pyridone (identified by Margolin as 5-methyl-1-(parahydroxyphenyl)-2-(1H) pyridone; *See* October 1, 1999 Response to European Official Action, attached herewith). Per Margolin, 5-methyl-1-(4'-hydroxyphenyl)-2-(1H) pyridone had a relative anti-fibrotic activity of 0.0, that is no anti-fibrotic activity at all. In comparison, Margolin indicated that pirfenidone had a relative anti-fibrotic activity of 1.0; 3-methyl-1-phenyl-2-(1H) pyridone had a relative anti-fibrotic activity of 1.0; 5-ethyl-1-

phenyl-2-(1H) pyridone a relative anti-fibrotic activity of 8.0; and 3-ethyl-1-phenyl-2-(1H) pyridone a relative anti-fibrotic activity of 6.0.

Applicants assert that the prosecution history of Margolin III, which must be considered as part of the prior art as a whole, teaches away from the use of 5-methyl-1-(4'-hydroxyphenyl)-2-(1H) pyridone in a *pharmaceutical* composition. One of ordinary skill in the art would not be motivated to invent a *pharmaceutical* composition comprising a compound identified as having no anti-fibrotic activity. Further, Applicant asserts the disclosures during the prosecution of Margolin III established accepted wisdom that 5-methyl-1-(4'-hydroxyphenyl)-2-(1H) pyridone had no anti-fibrotic activity. In light of the prior art as a whole and the fact that the presently claimed invention was derived contrary to accepted wisdom, Applicant asserts that the use of 5-methyl-1-(4'-hydroxyphenyl)-2-(1H) pyridone in *pharmaceutical* composition is non-obvious. Thus, Applicant respectfully requests that the rejection be withdrawn.

CONCLUSION

Applicants respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned. The Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment to Deposit Account No. 232415 (Attorney Docket No. 34569-716.831).

Respectfully submitted,

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